subtypes and to define the extent of variability within recognized subtypes. The secondary goal is to collect specimens representing these variants and recognized subtypes (A–I) to prepare a panel of sera collected from people whose infecting virus has been sequenced. The panel will be used to evaluate the sensitivity and specificity of existing and newly developed HIV antibody tests with regard to these strains and to assist, if necessary, in modifying these tests to broaden their sensitivity. Specimens will primarily be blood, but may include urine or oral fluids to evaluate diagnostic tests using these specimens. The research efforts in support of this CRADA are focused on the combined use of molecular and epidemiologic data to examine the question of whether certain HIV strains have distinctive patterns of transmission and disease progression in infected individuals.

The CRADA partner will be expected to provide both financial as well as scientific resources. Substantial involvement in specimen testing including molecular and biochemical analysis of viruses and viral components would be anticipated from the CRADA partner.

Respondents should provide evidence of expertise in the development and marketing of clinical diagnostics (prior experience with HIV preferred) and supporting data (e.g., publications, proficiency testing, certifications, resumes, etc.) of qualifications for the laboratory director and laboratory personnel who would be involved in the CRADA. The respondent will develop the final research plan in collaboration with CDC but should provide an outline of a research plan for review by CDC in judging applications.

Applicant submissions will be judged according to the following criteria:

1. Knowledge of molecular diagnostics including: epitope specific and recombinant based immunoassays, rapid tests, and nucleic acid based detection assays.
2. Working knowledge of nucleic acid sequencing, PCR, eukaryotic expression of recombinant antigens, and the large scale production of said products.
3. Operational experience in an international setting.
4. Procedural understanding of and experience in the development and marketing of HIV diagnostics in the United States.

This CRADA is proposed and implemented under the 1986 Federal Technology Transfer Act: Public Law 99–502, as amended.

The responses must be made to: Lisa Blake-DiSpigna, Program Analyst, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop C–19, Atlanta, GA 30333.

Dated: April 3, 1998.

Joseph R. Carter

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–9335 Filed 4–8–98; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee meeting.

Name: Ethics Subcommittee of the Advisory Committee to the Director, CDC.

Time and Date: 9 a.m.–3 p.m., April 27, 1998.

Place: CDC, Building 16, Room 5126, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 25 people.

Purpose: This subcommittee will anticipate, identify, and propose solutions to strategic and broad ethical issues facing CDC.

Matters To Be Discussed: Agenda items will include updates from the Associate Director for Science, Dixie E. Snider, M.D., followed by a discussion on issues surrounding the potential destruction of the smallpox virus, privacy and confidentiality of data collection, and scientific misconduct other than falsification, fabrication, and plagiarism.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Linda Kay McGowan, Acting Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D–24, Atlanta, Georgia 30333, telephone 404/639–7080.

Dated: April 2, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–9332 Filed 4–8–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Consolidation of United States Ports Designated To Conduct Rodent Infestation Inspections and Issue Deratting and Deratting Exemption Certificates

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services, HHS.

ACTION: Notice.

SUMMARY: In accordance with International and U.S. Federal regulations, the Centers for Disease Control and Prevention (CDC) has, for many years, inspected ships for rodent infestation and issued Deratting and Deratting Exemption Certificates at 18 major U.S. ports, as well as, by special arrangement, more than 100 smaller ports. To streamline these operations and increase cost effectiveness, CDC has consolidated the ports where it conducts these activities. As of October 1, 1997, CDC began conducting these inspections only at the ports of Baltimore, MD; Honolulu, HI: Houston, TX; Jacksonville, FL; Los Angeles, CA; Miami, FL; New Orleans, LA; New York, NY; San Francisco, CA; Savannah, GA; and Seattle, WA.

EFFECTIVE DATE: October 1, 1997.

FOR FURTHER INFORMATION CONTACT: David F. Rogers, Acting Chief, Program Operations Branch, Division of Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop E–03, Atlanta, Georgia 30333, (404) 639–8107, FAX (404) 639–2599, E-mail dfr1@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Background

This announcement provides notification of CDC's consolidation of the ports in the U.S. where rodent infestation inspections of ships are conducted and Deratting and Deratting Exemption Certificates are issued.

In accordance with Article 17 of the International Health Regulations, published by the World Health Organization (WHO), Geneva, the United States is required to (1) ensure that a sufficient number of U.S. ports have the capacity to inspect ships for the issue of Deratting Exemption Certificates and (2) depending upon the volume and incidence of international traffic, approve a number of these ports and maintain the capacity to perform rodent infestation inspections and issue

Deratting Certificates. The U.S. Public Health Service (PHS), specifically CDC, is delegated the responsibility for providing these services, as provided in 42 CFR Section 71.46.

Until a major restructuring in the 1970's greatly reduced the number of ports at which PHS assigned staff, these services were regularly performed by PHS staff at 18 large ports and more than 100 smaller ports, as manpower permitted. Since 1977, almost all inspections have been performed under contract by qualified pest control operators at these same ports, at no cost to the owners or agents of the ships inspected. In contrast, most nations pass along the costs associated with these services to those who benefit from them.

Deratting Exemption Certificates Not Required Since 1985

Because of worldwide derat certification activities and modern rat-proofing of ships, CDC determined in 1985 that no adverse impact on the public health would result from not requiring vessels from foreign ports to have a valid Deratting Exemption Certificate. As a result, the United States has not required Deratting Exemption Certificates for the last twelve years. This change resulted in a more economical rodent inspection program without any adverse consequences or increased risk to the public health.

Consolidation of Inspections and Deratting Certificate Issuance

CDC has now determined that consolidation of the number of ports at which inspections are conducted and Deratting Certificatess are issued will further economize the program without jeopardizing the public health.

Accordingly, beginning October 1, 1997, CDC started conducting rodent infestation inspections at eleven specified ports. Six of these ports were selected because of the proximity of PHS staff who can conduct inspections as necessary and ensure quality control. The five additional ports add geographic dispersion and provide additional opportunities for those seeking inspection services.

Article 20 of the International Health Regulations requires that notice be given to WHO when the list of ports designated in application of the International Health Regulations is changed. This notification has been made.

Applicability

The list of ports at which rodent infestation inspections are conducted and Deratting and Deratting Exemption Certificates are issued represents the only ports designated for this purpose. CDC staff or contract representatives are not available to conduct inspections at any other port.

Dated: April 3, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–9334 Filed 4–8–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89N–0474]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by May 11, 1998.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Geriatric Use Labeling for Human Prescription Drugs—21 CFR 201.57(f)(10)

In a final rule published on August 27, 1997 (62 FR 45313), FDA amended its regulations governing the content and format of labeling for human prescription drug products, including biological products, to include information on the appropriate use of drugs for persons age 65 years and older. The regulations facilitate access to this information by establishing a new ''Geriatric Use'' subsection in the labeling. The purpose of the regulation that will become effective on August 27, 1998, is to promote safe and effective use of prescription drugs among older people.

The regulations were issued under FDA's authority to regulate the labeling of prescription drugs and biological products, including sections 502(a), (f), and (j), and 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a), (f), and (j), and 355) and section 351 of the Public Health Service Act (42 U.S.C. 242).

In the final rule (62 FR 45313 at 45324), FDA requested comments on the information collection provisions of the new regulations. No comments were received in response to this request.

Respondents to this collection of information will be business, and other for-profit organizations, including small business and manufacturers.FDA estimated the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)	290	1	290	120	34,800

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.